REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 1, 8 and 15 have been amended herein. The support for these amendments can be found in the specification at paragraph [0039]. Care has been exercised to introduce no new matter. Accordingly, claims 1, 3, 5-8, 10, 12-15, 17, and 19-23 are pending and are in condition for allowance.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares that a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *Graham v. John Deere,* the Supreme Court counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966).

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02(I) (emphasis in original) (citing *StratoFlex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970)). Moreover, if an independent claim is

nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

"The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness . . . . To reach a proper determination of obviousness, the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. In view of all factual information, the examiner must then determine whether the claimed invention 'as a whole' would have been obvious at that time to that person. *Id* (emphasis added). Knowledge of applicant's disclosure must be put aside in reaching this determination . . . . [I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142.

"The key to supporting any rejection under 35 U.S.C. 103 is the **clear articulation of the reason(s)** why the claimed invention would have been obvious." MPEP § 2142 citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007) (emphasis added), which notes that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. Moreover, the Federal Circuit has stated that "'rejections on obviousness **cannot be sustained with mere conclusory statements**; instead, there must be some **articulated reasoning** with some rational underpinning to support the legal conclusion of obviousness.'" MPEP § 2142 (emphasis added) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). See also *KSR*, 127 S. Ct. at 1741 (quoting Federal Circuit statement with approval).

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ichikawa (Internal Medicine (July 2000) vol. 39, no. 7, pp. 523-524,

hereinafter "the Ichikawa reference") in view of Reinhoff et al., (U.S. 2002/0049772, hereinafter "the Reinhoff reference"), in view of Fey et al, (U.S. 2002/0038337, hereinafter "the Fey reference"), and further in view of Fiedotin et al. (U.S. 7,509,263, hereinafter "the Fiedotin reference"). As the combination of the Ichikawa, Reinhoff, Fey and Fiedotin references fail to teach or suggest all features of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1 as amended herein is generally directed to a computer-implemented method for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. The method includes the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information; inquiring if the person has a stored genetic test result value for the gene variant; accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions; determining from the hereditary information whether a parent of the person had the gene variant; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the

gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶[0032]-[0033], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

As amended herein, independent claim 8 is directed to a computer system embodied on one or more computer storage media having computer-executable instructions embodied thereon for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The system includes: a first displaying component that displays a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; a receiving component that receives from the user interface the clinician's inputs including at least one identifier of a clinical agent; a first accessing component for accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information; an inquiring component that inquires if the person has a stored genetic test result value for the gene variant; a second accessing component for accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions; a determining component for determining from the hereditary information whether a parent of the person had the gene variant; a utilizing component for utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; a generating component that generates an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and a second displaying component for displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person

has the gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶[0032]-[0033], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

Independent claim 15 as amended herein is generally directed to a computer storage medium containing instructions for a method for controlling a computer system for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The method comprising the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's input including at least one identifier of a clinical agent; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information; inquiring if the person has a stored genetic test result value for the gene variant; accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions; determining from the hereditary information whether a parent of the person had the gene variant; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶[0032]-[0033], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

Independent claims 1, 8 and 15 have been amended herein to recite a clarification of the systems and methods for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. In particular, the clarified process now recites the step of "determining from the hereditary information whether a parent of the person had the gene variant." Based upon this determination the invention of claims 1, 8 and 15 then computes the likelihood of the existence of the gene variant in the person being treated by the clinician. Advantageously, this process allows a clinician to incorporate the anticipated genetic information of a person into the clinical decision making process.

By way of contrast with the invention of claims 1, 8 and 15 the Ichikawa reference describes a method of genetic screening where a particular single nucleotide polymorphism may be used to disclose severe side effects or proper dosage for a patient. *See generally, Ichikawa* at p. 523. The Ichikawa reference describes that a patient with an autosomal recessive trait for thiopurine S-methyl transferase (TMPT) deficiency may experience marked leucopenia when treated with immunosuppressants including azathioprine. *Id.* Applicants respectfully submit that the Ichikawa reference fails to teach or suggest features of claim 1, 8 and 15. For instance, the Ichikawa reference fails to teach or suggest determining from hereditary information whether a parent of the person had the gene variant associated with an atypical event and utilizing the information about the presence of a gene variant a person's parents to determine the likelihood the person has the gene variant. The Ichikawa reference does not mention a computerized method of inquiring whether a patient's parents possessed a genetic mutation and utilizing that information to provide a clinician with an output regarding the likelihood has a gene variant.

The Office Action has acknowledged that the Ichikawa reference fails to teach the computer implemented aspects the invention of claim 1 including the aspect of accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events. *See Office Action* at p. 5. The Office asserts that the Reinhoff reference teaches the above-mentioned features.

The Reinhoff reference is directed to a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. *See Reinhoff* at ¶ [0010]. In the Reinhoff reference, when a polymorphism is known to be associated with a response to a known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. *Id.* at ¶ [0057].

Applicants respectfully submit that the feature of determining from the hereditary information whether a parent of the person had the gene variant associated with an atypical event, as described in the invention of claims 1, 8 and 15 is also absent from the Reinhoff reference. Rather, the Reinhoff reference discloses a computer program product that allows for comparing an individual's polymorphic profile with a plurality of polymorphic profiles to assist in performing clinical trials by ascertaining whether a particular nucleic acid variation affects the efficacy of a pharmaceutical. *Id.* at ¶¶ [0011]-[0014]. The Reinhoff reference describes identifying a "susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain diseases." *Id.* at ¶ [0010]. The genetic screening methods in the Reinhoff reference consist of genetic tests involving using polymerase chain reaction (PCR) and other polymerase driven amplification assays to determine an individual's polymorphic profile. *See generally, id.* at ¶¶ [0027]-[0038]. Nowhere does Reinhoff mention, determining from the hereditary information of a person whether a parent of said person had a gene variant associated

with an atypical event. Additionally, Reinhoff reference is silent on utilizing the hereditary information for the person to determine the likelihood the person has the gene variant. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

Applicants respectfully submit that the Fey reference fails to cure the deficiencies of the Ichikawa and Reinhoff references. The Fey reference describes a centralized health screening and management system. *See Fey* at [0020]. In Fey, data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. *Id.* The Fey reference does not disclose determining from the hereditary information of a person whether a parent of said person had a gene variant indicative of an atypical event. Additionally, Fey is silent on utilizing the hereditary information for the person to determine the likelihood the person has the gene variant. The Fey reference merely discusses storing health data in a manner that is accessible. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey reference, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

Applicants respectfully submit that the feature of determining from the hereditary information of a person whether a parent of said person had a gene variant indicative of an atypical event, as described in the invention of claims 1, 8 and 15 is also absent from the Fiedotin reference. The Fiedotin reference describes a method for providing physicians access to current health care industry information including formulary data, and clinical and practice management information at the point of care on a handheld electronic device. *See Fiedotin* at Abstract. In Fiedotin, health care data is compiled from various sources such as clinical databases, the

internet. Id. at col. 9 lines 27-29. The health care data includes information such as dosing, co-payment, drug pricing, drug-drug reaction and adverse reaction information. *Id.* at lines 30-35. Nowhere does Fiedotin mention determining from the hereditary information of a person whether a parent of said person had a gene variant indicative of an atypical event. Rather, Fiedotin merely describes a method for distributing general medical information stored on a computer system to a physician via a handheld computing device. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey and Fiedotin references, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

As the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey and Fiedotin references fails to teach or suggest all the limitations of the independent claims 1, 8 and 15, a *prima facie* case of obviousness has not been made for independent claims , 8 and 15 with respect to these references. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of these claims. Further, as claims 5-7, 10, 12-14, 17 and 19-21 depend directly or indirectly from amended independent claims 1, 8 and 15, Applicants request withdrawal of the rejection of these claims as well.

CONCLUSION

For at least the reasons stated above, claims 1, 3, 5- 8, 10, 12-15, 17, and 19-23 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or jdickman@shb.com (such communication via email is herein expressly granted) – to resolve the same. In the event it is determined necessary, the Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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